REMARKS/ARGUMENTS

Reconsideration of this application is awaited. Claims 18-34 are in the case.

I. THE 35 U.S.C. §112, FIRST PARAGRAPH, REJECTION

Claims 18-33 stand rejected under 35 U.S.C. §112, first paragraph, on the ground that the specification, while enabling for the "treatment of vaginal fungal infections", allegedly does not reasonably provide enablement for the "prevention" of vaginal fungal infections. The rejection is respectfully traversed.

At page 4 of the Action, it is stated that:

> "All of the working examples provided by the specification are directed toward the treatment rather than prevention of fungal infections."

However, contrary to the above statement, Examples 4 and 5 (pages 10-12 of the application) clearly relate to the prevention of vaginal fungal infections, and do not refer to the treatment of vaginal fungal infections. In light of this disclosure, it is clear that one of ordinary skill in the art, as of the filing date of the application, would have been enabled to carry out the invention as claimed with respect to both treatment and prevention of vaginal fungal infections according to the claimed method. Withdrawal of the lack of enablement rejection is respectfully requested.

II. THE OBVIOUSNESS REJECTION

Claims 18-33 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Zeng (U.S. Patent No. 6,770,306) in view of Hotzel *et al*. (U.S. Patent No. 5,371,107) (Hotzel). The rejection is respectfully traversed.

As claimed, the invention provides a method for the prevention or treatment of vaginal fungal infections. The method comprises administering a formulation comprising ascorbic acid or a physiologically acceptable salt thereof to a patient in need of such prevention or treatment. The formulation is administered after completion of a standard treatment of the patient for bacterial, fungal or protozoarian infections.

As stated in the present specification (page 6), ascorbic acid creates an unsuitable environment for the germination of new vegetative forms from fungal spores. Thus, when a standard treatment against bacterial, fungal or protozoarian infection is performed, later fungal infections may arise. This is because the standard therapy can create conditions which are favorable for growth of certain germs that were not able to grow prior to such standard therapy due to competition for nutriments within the vagina (primarily glycogen and vaginal sugars).

Thus, vaginal fungal infections often arise as a result of previously administered antibiotic and/or antiprotozoarian agents which change the vaginal flora and kill bacteria. The absence of such bacteria (both pathogen or normal saprophyte bacteria, e.g. lactobacillus) creates a favorable environment for fungal growth due the germination of spores which are ubiquitous. It is known that fungi cannot grow where bacteria exist unless the fungi themselves produce some antibiotic substances (penicillin and all major antibiotics were discovered by study of mold growth in dirty

environments). In the case of fungal infections arising subsequent to antifungal therapy, vaginal fungal infections often are the result of growth of resistant strains against the previous therapy.

The present invention is based on the discovery that ascorbic acid creates an unfavorable environment to the germination of fungal spores after a standard treatment against bacterial, fungal or protozoarian infections. As discussed below, this is not suggested by Zeng or Hotzel, taken singly or in combination.

Zeng discloses that fungal vaginitis can be treated with a pharmaceutical composition for reducing vaginal acidity and notes that raising of vaginal acidity leads to damage of the vaginal mucosa, which can result in vaginitis (Abstract; col. 2, lines 15-20; col. 3, lines 42-51; col. 6, lines 6-13, and 35-40). It is well known that in order to reduce acidity, the pH must be increased. The Zeng composition contains aminoacids, oligopeptides and a basic substance such as sodium carbonate in order to **reduce** the vaginal acidity by raising the pH.

Zeng provides no suggestion of a method of preventing or treating vaginal fungal infections using a formulation comprising ascorbic acid or a physiologically acceptable salt thereof. In addition, Zeng provides no suggestion of administering such a formulation after completion of a standard treatment against bacterial, fungal or protozoarian infections, as presently claimed.

It is known that ascorbic acid increases acidity and thus lowers the pH. One of ordinary skill in this art, as of the filing date of the present application, would not therefore have been motivated to arrive at the presently claimed method based on Zeng's disclosure of using a pharmaceutical composition that aims to reduce vaginal

acidity, and also the Zeng disclosure that raising of vaginal acidity leads to damage of the vaginal mucosa, which can result in vaginitis (col. 2, lines 15-20). Zeng therefore leads **away** from the presently claimed method.

Hotzel does not cure the deficiencies of Zeng discussed above. Hotzel discloses the topical use of vitamin C (ascorbic acid) to eliminate the potential pathogenic bacteria by acidification. However, based on this disclosure, one of ordinary skill in the art would not have been motivated to combine Zeng and Hotzel, since Zeng aims to reduce vaginal acidity, whereas Hotzel discloses the use of an acidic material (ascorbic acid). Moreover, even if one of ordinary skill had contemplated combining Zeng and Hotzel (it is believed this would not have occurred), the presently claimed method would not have resulted or have been rendered obvious thereby because, according to the claimed method, ascorbic acid is administered to women who have already completed a standard treatment against bacterial, fungal or protozoarian infections.

The cited art, taken singly or in combination, does not suggest the claimed methodology. Withdrawal of the obviousness rejection is respectfully requested.

III. AMENDMENTS

The claims have been amended to improve their form. No new matter is entered.

Favorable action is awaited.

Respectfully submitted,

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